

Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to indicate that the first fiber film referred to therein has a thickness in a range of 3-35 μm (based on page 4, line 20 of the specification), and the other fiber film has a thickness in a range of 7-70 μm (based on page 6, line 9 of the specification).

Applicant takes the position that the amendments to claim 1 should be entered, even though they are presented after a final rejection, since the effect of the amendments is to clearly place the application in condition for allowance, as will be apparent from the following remarks.

That is, the patentability of the presently claimed invention after entry of the foregoing amendments, over the disclosures of the references relied upon by the Examiner in rejecting the claims, will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1-2, 5-6, 8, 11, 16, 19 and 22-23 under 35 U.S.C. §103(a) as being unpatentable over Mooney et al. (US '031) in view of Muta et al. (US '431) is respectfully traversed.

I. Comparison with Mooney et al.

1. The present invention relates to a thin aqueous cataplasm prepared by laminating an adhesive layer on a support, and said support consisting of a fiber film **having a thickness in a range of 3-35 μm** prepared by heat-fusing a soft plastic resin on a composite fiber prepared by entangling a natural fiber and a soft plastic fiber, or said support consisting of a fiber film **having a thickness in a range of 7-70 μm** prepared by heat-fusing a plastic resin having a soft part and a hard part in common on a fiber consisting of a plastic having a soft part and hard part in common, and said adhesive layer consisting of 25 to 60 w/w% of water, a moisture-retaining agent, polyacrylic acid and/or its salt, a cellulose derivative selected from the group consisting of carboxymethyl cellulose sodium, hydroxypropyl cellulose and hydroxymethyl cellulose, a slightly soluble polyvalent metal salt and a pH controlling agent, and its pH is adjusted to 4 to 6.

2. Mooney et al. relate to an occlusive wound care dressing comprising (1) a backing material, (2) an adhesive, (3) a support material, (4) an occlusive composition and (5) a porous covering material as shown in Fig. 7A and as claimed in claim 1.

Mooney et al. mention that the dressings may be coated directly onto a film or fiber substrate which is, in turn, applied to the wound and surrounding skin; that such films may be

composed of one or more polymer such as polyethylene; and that the films may be continuous or discontinuous (column 6, lines 21-29).

Mooney et al. also mention that the dressings may be coated onto a fiber substrate which, in turn, is **adhesively or otherwise attached** to a film substrate; that examples of fiber substrates are fabrics that are knitted such as modified entangled fiber composed of rayon polyesters, or those that are woven, such as flexible fabrics composed of rayon-nylon blends; that a nonwoven fiber substrate may also be used, such as 90:10 polypropylene-rayon blends, or the like; that the dressings can be coated onto a film or fiber material and then further applied to a secondary substrate which holds the dressing in place over the wound; and that type of secondary substrates are films or woven or nonwoven fabrics **with pressure sensitive adhesives** (column 6, lines 30-41).

The Examiner stat that Mooney et al. disclose a structure occlusive dressing which can be applied directly to a wound, or may be coated directly onto a film or fiber substrate which is, in turn applied to the wound and surrounding skin; that the films may be composed of one or more polymers including polyethylene, which is a soft plastic resin and the specific resin of claims 6 and 14-16; and that Mooney et al. disclose fiber substrates including fabrics that are knitted such as modified entangled fiber composed of rayon polyesters, such as 90:10 polypropylene-rayon blends, which is the particular combination disclosed in instant claim 6 and 14-16.

Example 21 (column 10, lines 42-50) of Mooney et al. discloses that the support material 110 used in the bandage was a nonwoven fabric comprising about 90% by weight of polypropylene fibers and about 10% by weight of rayon fibers. The basis weight of this fabric was 3.7oz/yd² (125g/m²) and had a thickness of about 34 mils (864 µm). The reference also states that the support materials may comprise nonwoven fabrics other the one described above, and in addition, other materials, such as foams, woven fabrics (e.g., gauze), knitted fabrics and the like may be used.

3. However, the present invention and Mooney et al. are distinctively different in object, constitution and effect as explained below in detail.

(1) The object of the present invention is to provide a **thin** aqueous cataplasma, but the dressing of Mooney et al. is not intended to provide a thin one, but is to provide a structure wound dressing which remains in place and does not flow, but has an ointment-like feel.

(2) Therefore, the dressing of Mooney et al. has a porous cover as an essential component, but the cataplasm of the present invention does not need such a porous covering material.

(3) The dressing of Mooney et al. relates to a kind of gelling preparation. On the other hand the present cataplasm does not belong to a gelling preparation.

(4) In the dressing of Mooney et al., a support material and a backing material are combined with a **pressure sensitive adhesive** (or otherwise: no concrete description). Therefore, there is a possibility that the adhesive used therein permeates into an occlusive composition through a support material, or that an occlusive composition permeates into the adhesive to impart deleterious effects to the dressing.

On the other hand, in the present cataplasm the fiber film is prepared by heat-fusing a soft plastic resin on a composite fiber, or by heat-fusing a plastic resin having a soft part and a hard part in common on a fiber consisting of a plastic having a soft part and hard part in common. Therefore there is no fear of an adhesive permeating into an adhesive layer.

(5) In the present cataplasm the fiber film prepared by heat-fusing a soft plastic resin on a composite fiber, or by heat-fusing a plastic resin having a soft part and a hard part in common on a fiber consisting of a plastic having a soft part and hard part in common is well matched to an adhesive layer and is combined with it. In addition, the fiber film has a lot of untreated (unfused) fiber-residues, and therefore, the fiber film and an adhesive layer containing a drug and an adhesive are strongly connected or combined (see page 4, lines 21-26 of the specification). When the present catplasms are peeled off from the skin, even part of the adhesive will not remain on the skin. This is a very significant characteristic property of the present catplasms. On the other hand in the dressing of Mooney et al., binding between a support material and an occlusive material is not so strong (the binding is not intended to be strong) and therefore, in case of peeling off, there is a possibility that the occlusive composition will still remain on the skin.

(6) As explained above, the subject matter of the present invention is distinctively different from the dressing disclosed in Mooney et al. in object, constitution and effect.

II. Comparison with Muta et al.

1. Muta et al. disclose catplasms comprising a base of a gel patch containing water, a moisturizer, a water soluble polymers, a cross linking agent and an additive. The reference

describes that the inventors have found that a gel patch containing steroids as effective ingredients can comply with the intended purpose even at a dissolution state, when the gel patch is blended with a considerably larger volume of **crotamiton** as a stabilizer, compared to that employed in conventional sticking dosage forms, and with a **surfactant** having a predetermined blend ratio to crotamiton. The support is described in column 6 lines 18 to 59, further in Example 1 (column 7, lines 58-64). However a support related to the present invention is never described therein.

2. As explained above, the subject matter of the present invention is distinctively different from the gel patch disclosed in Muta et al. in object, constitution and effect.

3. In addition, there is no motivation for the skilled person in the art to combine Mooney et al. and Muta et al. Even if both references are combined, it would be impossible for the skilled person to arrive at the subject matter of the present invention.

For these reasons, Applicant takes the position that the presently claimed invention is clearly patentable over the applied references.

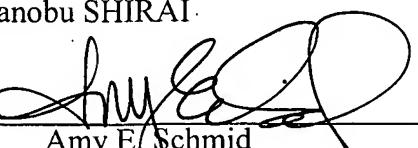
Therefore, in view of the foregoing amendments and remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

NOTE: Photos of a support prepared by Example 1 of the present application are enclosed herewith. Photo 1 is a view of the surface on the film side of the support. Photo 2 is a view of the surface on the adhesive layer side of the support. Photo 3 is a view of a cross section of the support.

Respectfully submitted,

Sadanobu SHIRAI

By



Amy E. Schmid

Registration No. 55,965

for

Michael R. Davis

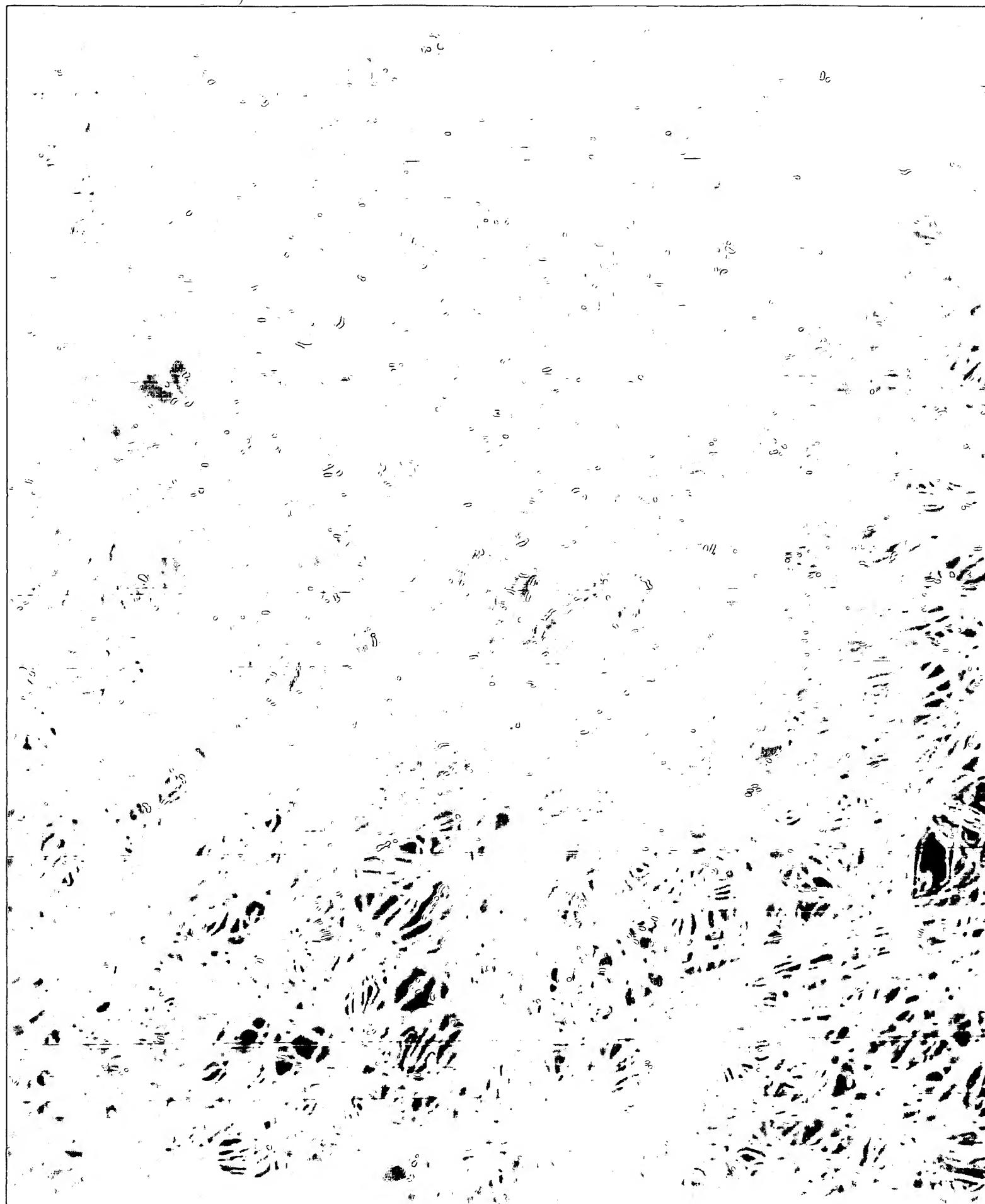
Registration No. 25,134

Attorney for Applicant

MRD/pth
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
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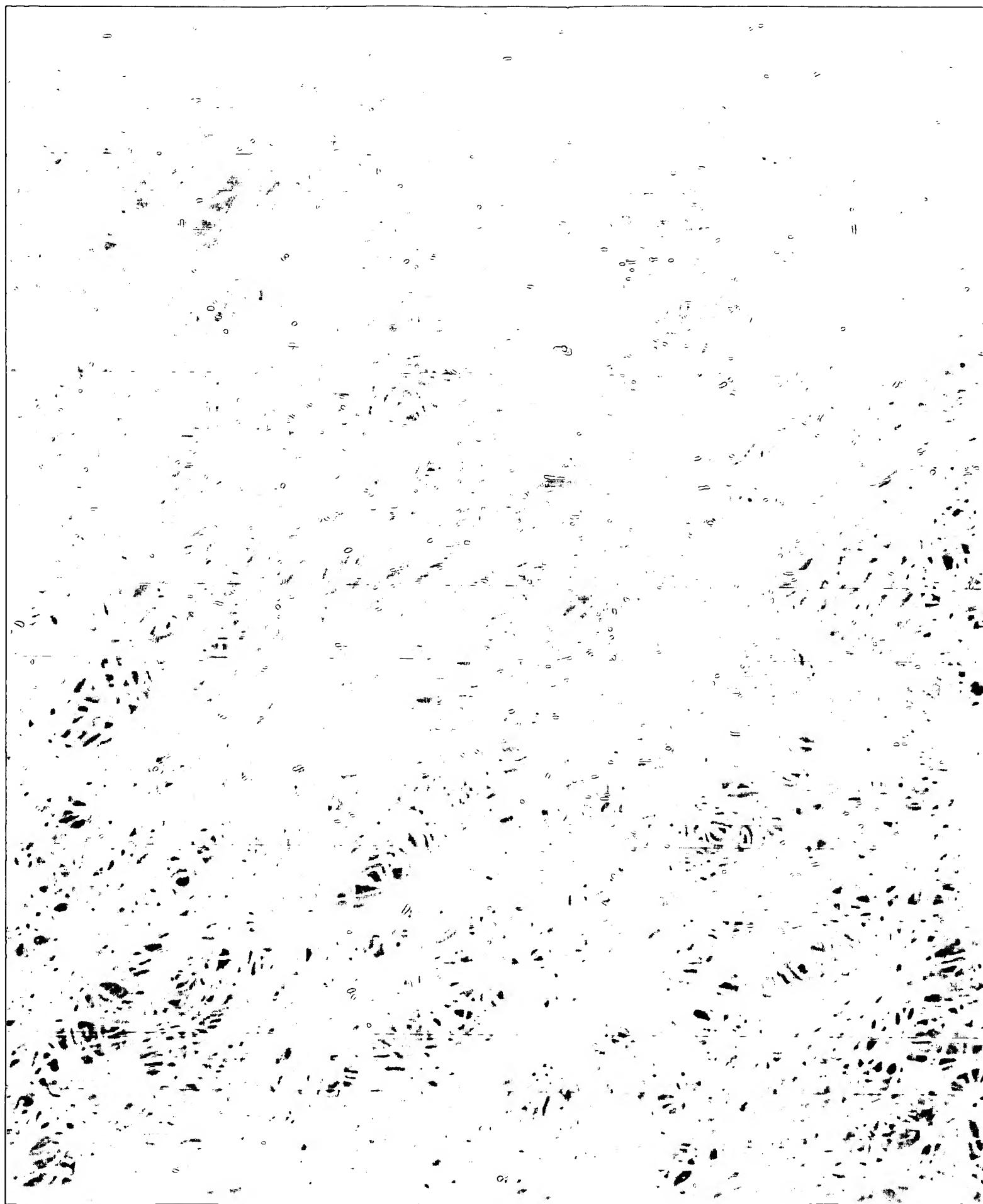
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Photo 1



Serial No. 10/542,932

Photo Z.



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